

Preliminary Amendment and Response
Filed in connection with RCE of
U.S. Serial No. 09/937,643

In the Claims:

Kindly amend the claims as follows:

Claims 1-25 (cancelled)

26. (Currently Amended) A method of treating prostate cancer comprising administration of a composition comprising:

(a) mycobacterial DNA (B-DNA) obtained from a disrupted mycobacterium using DNase-free reagents in order to at least partially preserve the DNA; and

(b) a pharmaceutically acceptable carrier

to an animal or human having prostate cancer in an amount effective to have an antineoplastic effect on prostate cancer in the animal or human having the prostate cancer.

27. (Previously Amended) The method of Claim 26, wherein the mycobacterial DNA is obtained from *M. smegmatis*, *M. kansaii*, *M. fortuitum*, *M. tuberculosis*, *M. bovis*, *M. vaccae*, *M. avium* or *M. phlei*.

28. (Previously Amended) The method of Claim 26, wherein the mycobacterial DNA (B-DNA) is obtained from *M. phlei*.

29. (Previously Amended) The method of Claim 26, wherein the pharmaceutically acceptable carrier is mycobacterial cell wall (BCC).

30. (Previously Amended) The method of Claim 29, wherein the mycobacterial DNA (B-DNA) is preserved and complexed on the mycobacterial cell wall (BCC).

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31. (Previously Amended) The method of Claim 26, wherein the pharmaceutically acceptable carrier is *M. phlei* cell wall (MCC).

32. (Previously Amended) The method of Claim 31, wherein *M. phlei* DNA is preserved and complexed on the *M. phlei* cell wall (MCC).

33. (Previously Amended) The method of Claim 26, wherein the prostate cancer is hormone-sensitive prostate cancer.

34. (Previously Amended) The method of Claim 33, wherein the hormone is an androgen.

35. (Previously Amended) The method of Claim 34, wherein the androgen is testosterone.

36. (Currently Amended) [The method of Claim 26,]
A method of treating prostate cancer comprising administration of a composition comprising:

(a) mycobacterial DNA (B-DNA) obtained from a disrupted mycobacterium using DNase-free reagents in order to at least partially preserve the DNA; and

(b) a pharmaceutically acceptable carrier

to an animal or human having prostate cancer in an amount effective to have an antineoplastic effect on prostate cancer in the animal or human having the prostate cancer,

wherein the antineoplastic effect is inhibition of proliferation of cancer cells in the prostate, induction of apoptosis in the cancer cells in the prostate, induction of cytokine synthesis in the cancer cells in the prostate, or induction of cytokine synthesis by immune system cells in the prostate.

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37. (Previously Amended) The method of Claim 36, wherein the cytokine is IL-12 or TNF- α .

38. (Previously Amended) The method of Claim 26, wherein the pharmaceutically acceptable carrier is a solid carrier, a liquid carrier, or combination of a solid and liquid carrier.

39. (Previously Amended) The method of Claim 26, further comprising administration of anti-androgenic agents, chemotherapeutic agents, steroids, or immunological agents.

40. (Currently Amended) A method of treating prostate cancer comprising administration of a composition comprising:

(a) mycobacterial DNA (B-DNA) obtained from a disrupted mycobacterium using DNase-free reagents in order to at least partially preserve the DNA, the mycobacterial DNA preserved and complexed on mycobacterial cell wall (BCC); and

(b) a pharmaceutically acceptable carrier

to an animal or human having prostate cancer in an amount effective to have an antineoplastic effect on prostate cancer in the animal or human having the prostate cancer.

41. (Previously Amended) The method of Claim 40, wherein the mycobacterial DNA is obtained from *M. smegmatis*, *M. kansaii*, *M. fortuitum*, *M. tuberculosis*, *M. bovis*, *M. vaccae*, *M. avium* or *M. phlei*.

42. (Previously Amended) The method of Claim 40, wherein the mycobacterial DNA is obtained from *M. phlei*.

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43. (Previously Amended) The method of Claim 40, wherein the mycobacterial cell wall is *M. phlei* cell wall (MCC).

44. (Previously Amended) The method of Claim 40, wherein the prostate cancer is hormone-sensitive prostate cancer.

45. (Previously Amended) The method of Claim 44, wherein the hormone is an androgen.

46. (Previously Amended) The method of Claim 45, wherein the androgen is testosterone.

47. (Previously Amended) The method of Claim 40, wherein the antineoplastic effect is inhibition of proliferation of cancer cells in the prostate, induction of apoptosis in cancer cells in the prostate, induction of cytokine synthesis by cancer cells in the prostate, or induction of cytokine synthesis by immune system cells in the prostate.

48. (Currently Amended) [The method of Claim 47,]
A method of treating prostate cancer comprising administration of a composition comprising:
(a) mycobacterial DNA (B-DNA) obtained from a disrupted mycobacterium using DNase-free reagents in order to at least partially preserve the DNA, the mycobacterial DNA preserved and complexed on mycobacterial cell wall (BCC); and
(b) a pharmaceutically acceptable carrier
to an animal or human having prostate cancer in an amount effective to have an antineoplastic effect on prostate cancer in the animal or human having the prostate cancer,

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wherein the antineoplastic effect is induction of cytokine synthesis by cancer cells in the prostate or induction of cytokine synthesis by immune system cells in the prostate, and wherein the cytokine is IL-12 or TNF- α .

49. (Previously Amended) The method of Claim 40, wherein the pharmaceutically acceptable carrier is a solid carrier, a liquid carrier, or a combination of a solid and liquid carrier.

50. (Previously Amended) The method of Claim 40, further comprising administration of anti-androgenic agents, chemotherapeutic agents, steroids, or immunological agents.

Claims 51-56 (previous numbering mistakes – claims not pending)

Claims 57-65 (cancelled)

Kindly add the following new claims:

66. (Newly presented) A method of treating prostate cancer comprising administration of a composition comprising:
(a) mycobacterial DNA (B-DNA) obtained from a disrupted mycobacterium using DNase-free reagents in order to at least partially preserve the DNA; and
(b) a pharmaceutically acceptable carrier
to an animal or human having prostate cancer in an amount effective to have an antineoplastic effect on prostate cancer in the animal or human having the prostate cancer,
wherein the amount of M-DNA administered is from about 0.00001 to about 200mg/kg per dose.

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67. (Newly presented) The method of claim 69, wherein the amount of M-DNA administered is from about 0.0001 to about 100mg/kg per dose.

68. (Newly presented) The method of claim 69, wherein the amount of M-DNA administered is from about 0.001 to about 50mg/kg per dose.

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